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AUGHENBAUGH, WALTER	
ART UNIT	**PAPER NUMBER**
1772	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/767,269	KAPPELER, KURT-ROBERT	
	Examiner	Art Unit	
	Walter B. Aughenbaugh	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-13 and 15-20* is/are pending in the application.

4a) Of the above claim(s) *15-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-13,19 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 9, 2007 (Amdt. B) has been entered.

Acknowledgement of Applicant's Amendments

2. Applicant's amendments in claims 1, 6, 19 and 20 in the Amendment filed February 9, 2007 (Amdt. B) have been received and considered by Examiner.

Election/Restrictions

3. Applicant did not cancel the nonelected claims or take other appropriate action in Amdt. B as was required in paragraph 5 of the previous Office Action mailed August 9, 2006 for the reply to be considered a complete reply.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1, 3, 4, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. in view of Carden, Jr. et al.

In regard to claim 1, Stone et al. teach a multi-layer hose (balloon sheath, item 40) comprising an opaque, extrudable first layer (item 42), an opaque, extrudable second layer (item 44) connected to the first layer (col. 5, lines 29-32 and Fig. 2) and more than one marking

sections that are arranged between the first layer and the second layer (radiopaque marker, col. 5, lines 43-50) and that are adapted to be read making use of X-rays (since the marking sections are radiopaque). The first and second layers of Stone et al. are opaque because the materials of the layer are polymeric materials that are not disclosed as transparent (any layer that is not transparent has some degree of opacity). The first and second layers of Stone et al. are extrudable because Stone et al. teach that the first layer (item 42) is formed of an elastic material such as latex or silicone (col. 5, lines 51-57), both of which are extrudable as evidenced by col. 21, lines 13-21 of U.S. 5,928,200 to Thorne et al., and that the second layer (item 44) is formed of such materials as PET and nylon, both of which are extrudable as evidenced by col. 3, lines 8-12 of U.S. 6,443,925 to Schaible et al.

The recitation "each marking section comprising more than one letter and/or more than one number" is a printed matter limitation that has not been given patentable weight based upon the guidelines set forth in MPEP 2112.01 III:

> III. PRODUCT CLAIMS - NONFUNCTIONAL PRINTED MATTER DOES NOT DISTINGUISH CLAIMED PRODUCT FROM OTHERWISE IDENTICAL PRIOR ART PRODUCT
>
> Where the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art. *In re Ngai*, **>367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004)< (Claim at issue was a kit requiring instructions and a buffer agent. The Federal Circuit held that the claim was anticipated by a prior art reference that taught a kit that included instructions and a buffer agent, even

> though the content of the instructions differed.). See also *In re Gulack*, 703 F.2d 1381, 1385-86, 217 USPQ 401, 404 (Fed. Cir. 1983)("Where the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability .... [T]he critical question is whether there exists any new and unobvious functional relationship between the printed matter and the substrate.").
>
> MPEP 2112.01 III.

The actual form of the markings does not define or contribute to the function of the device. The recitation "each marking section comprising more than one letter and/or more than one number" does not recite a new and unobvious functional relationship between the printed matter and the substrate; therefore, the printed matter recitation "each marking section comprising more than one letter and/or more than one number" bears no patentable weight. *In re Gulack.* Furthermore, the fact that the claims fail to specify which languages, which numbering systems and/or code equivalents (Morse code, Braille, bar, etc...), if any, fall within the scope of the recitation "each marking section comprising more than one letter and/or more than one number" further supports the fact that the content/shape of the markings is not germane to the function of the device and therefore that these shape/content features bear no patentable weight.

Stone et al. teach that suitable materials for the markers are platinum and gold (col. 4, lines 51-57). Stone et al. teach that the marker bands enable visualization of the axial position of the sheath relative to other radiopaque structures (col. 5, lines 47-50).

Stone et al. fail to explicitly teach that the radiopaque markers are provided in a longitudinally spaced relationship with one another in a recurring mode of arrangement.

Carden, Jr. et al. disclose an implantable biomedical plastic strand (item 900, Fig. 11) that comprises bands of an X-ray absorbing material such as gold or platinum as radiopaque markers that are provided in a longitudinally spaced relationship with one another in a recurring mode of arrangement (Fig. 11 and col. 20, lines 30-35 and col. 21, lines 14-26). Therefore, since Stone et al. teach that the marker bands enable visualization of the axial position of the sheath relative to other radiopaque structures (col. 5, lines 47-50), one of ordinary skill in the art would have recognized to have applied the radiopaque bands of Stone et al. in a longitudinally spaced relationship with one another in a recurring mode of arrangement along the hose of Stone et al. in order to enable a healthcare worker to precisely visualize the location of the hose within the body and of particular portions of the hose along its length (relative to other radiopaque structures as taught by Stone et al.) since it is well known to provide a medical implant with radiopaque markers in a longitudinally spaced relationship with one another in a recurring mode of arrangement for visualization of the device as taught by Carden, Jr. et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have applied the radiopaque bands of Stone et al. in a longitudinally spaced relationship with one another in a recurring mode of arrangement along the hose of Stone et al. in order to enable a healthcare worker to precisely visualize the location of the hose within the body and of particular portions of the hose along its length since it is well known to provide a medical implant with radiopaque markers in a longitudinally spaced relationship with one another in a recurring mode of arrangement for visualization of the device as taught by Carden, Jr. et al.

In regard to claim 3, Stone et al. teach that the first layer (item 42) is formed of an elastomer such as latex or silicone (col. 5, lines 51-57).

In regard to claim 4, Stone et al. teach that the elastomer is a rubber because elastomers are rubbers.

In regard to claims 19 and 20, the recitations "the marking sections comprise a date or a production number" of claim 19 and "the marking sections indicate a material" of claim 20 are printed matter limitations that have not been given patentable weight based upon the guidelines set forth in MPEP 2112.01 III, including the *In re Gulack* holding, as discussed above in regard to claim 1.

6. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. in view of Carden, Jr. et al. and in further view of Hostettler et al.

Stone et al. and Carden, Jr. et al. teach the hose as discussed above. Stone et al. teach that the outer later, item 42, is formed from a wide variety of elastic materials (col. 5, lines 51-57).

Stone et al. and Carden, Jr. et al. fail to explicitly teach that the rubber is an ethylene acrylate rubber.

Hostettler et al., however, disclose that ethylene/alkyl acrylate copolymer rubbers are a suitable material for use in catheters (col. 9, lines 6-13). Therefore, one of ordinary skill in the art would have recognized to have used the ethylene/alkyl acrylate copolymer rubber taught by Hostettler et al. as the elastic material of outer later, item 42, of Stone et al. of the hose taught by Stone et al. and Carden, Jr. et al. since ethylene/alkyl acrylate copolymer rubber is a well known material for use in catheters as taught by Hostettler et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the ethylene/alkyl acrylate copolymer rubber taught by Hostettler et al. as the elastic material of outer later, item 42, of Stone et al. of the hose taught by Stone et al. and

Carden, Jr. et al. since ethylene/alkyl acrylate copolymer rubber is a well known material for use in catheters as taught by Hostettler et al.

7. Claims 6 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. in view of Carden, Jr. et al. and in further view of Shu.

Stone et al. and Carden, Jr. et al. teach the hose as discussed above.

In regard to claim 6, Stone et al. and Carden, Jr. et al. fail to explicitly teach that the radiopaque markers are formed by an ink.

Shu, however, disclose a balloon catheter comprising radiopaque ink as a radiopaque marker or markers for tracking the exact location of the balloon catheter inside a patient (col. 9, line 61-col. 10, line 11). Therefore, one of ordinary skill in the art would have recognized to have used a radiopaque ink as the radiopaque marker or markers of the hose taught by Stone et al. and Carden, Jr. et al. since radiopaque ink is a well known radiopaque marker for balloon catheter devices as taught by Shu.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a radiopaque ink as the radiopaque marker or markers of the hose taught by Stone et al. and Carden, Jr. et al. since radiopaque ink is a well known radiopaque marker for balloon catheter devices as taught by Shu.

In regard to claim 11, Stone et al., Carden, Jr. et al. and Shu teach the hose as discussed above. The limitation of claim 11 "wherein the ink is applicable to the hose by means of a printer" has been given little patentable weight since the method used to apply the ink to the hose is not germane to the issue of patentability of the hose itself. In regard to claims 12 and 13, the limitations of these claims have not been given patentable weight since the type of apparatus

used to apply the ink to the hose (in regard to claims 11-13) are not germane to the issue of patentability of the hose itself.

While Stone et al. and Shu fail to explicitly teach that the ink is applicable to the hose by means of a printer, Carden, Jr. et al. disclose an implantable biomedical plastic strand (item 900, Fig. 11) that comprises bands of radiopaque ink that are printed onto the plastic strand via inkjet printing technology (col. 20, lines 30-35 and col. 21, lines 14-23). Therefore, one of ordinary skill in the art would have recognized to have printed radiopaque ink onto the hose taught by Stone et al., Carden, Jr. et al. and Shu via an inkjet printer since it is well known to print radiopaque ink onto a medical device via an inkjet printer as taught by Carden, Jr. et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have printed radiopaque ink onto the hose taught by Stone et al., Carden, Jr. et al. and Shu via an inkjet printer since it is well known to print radiopaque ink onto a medical device via an inkjet printer as taught by Carden, Jr. et al.

8. Claims 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. in view of Carden, Jr. et al. and in further view of Shu and in further view of Kelderman et al.

Stone et al., Carden, Jr. et al. and Shu teach the hose as discussed above.

Stone et al., Carden, Jr. et al. and Shu fail to explicitly teach that the ink contains an iodine compound and that the ink contains potassium iodide.

Carden, Jr. et al., however, disclose an implantable biomedical plastic strand (item 900, Fig. 11) that comprises bands of radiopaque ink that are printed onto the plastic strand via inkjet printing technology (col. 20, lines 30-35 and col. 21, lines 14-23). Furthermore, Kelderman et al. teach an inkjet ink that comprises potassium iodide as a dye (KI, an iodine compound, col. 7,

lines 59-65 and col. 1, line 61-col. 2, line 8). Therefore, one of ordinary skill in the art would have recognized to have printed radiopaque ink onto the hose taught by Stone et al., Carden, Jr. et al. and Shu via inkjet printing technology since it is well known to print radiopaque ink onto a medical device via inkjet printing technology as taught by Carden, Jr. et al. and to have used an inkjet ink comprising potassium iodide as the ink since potassium iodide is a well known dye for use in inkjet ink as taught by Kelderman et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have printed radiopaque ink onto the hose taught by Stone et al., Carden, Jr. et al. and Shu via inkjet printing technology since it is well known to print radiopaque ink onto a medical device via inkjet printing technology as taught by Carden, Jr. et al. and to have used an inkjet ink comprising potassium iodide as the ink since potassium iodide is a well known dye for use in inkjet ink as taught by Kelderman et al.

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. in view of Carden, Jr. et al. and in further view of Shu and in further view of Kelderman et al. and in further view of Carroll.

Stone et al., Carden, Jr. et al., Shu and Kelderman et al. teach the hose as discussed above.

Stone et al., Carden, Jr. et al., Shu and Kelderman et al. fail to explicitly teach that the ink contains an iodine compound and that the ink contains iopamidole.

Carden, Jr. et al., however, disclose an implantable biomedical plastic strand (item 900, Fig. 11) for the treatment of tumors (col. 1, lines 7-9 and 35-47) that comprises bands of radiopaque ink that are printed onto the plastic strand via inkjet printing technology (col. 20,

lines 30-35 and col. 21, lines 14-23). Furthermore, Carroll discloses that ethanolamine oleate iopamidole is used in the preparation of a tumor for treatment (col. 5, line 58-col. 6, line 2 and col. 3, line 66-col. 4, line 18). Therefore, one of ordinary skill in the art would have recognized to have printed radiopaque ink onto the hose taught by Stone et al., Carden, Jr. et al., Shu and Kelderman et al. via inkjet printing technology since it is well known to print radiopaque ink onto a medical device via inkjet printing technology as taught by Carden, Jr. et al. and to have used an inkjet ink comprising ethanolamine oleate iopamidole as the ink so that the ink may contribute to the preparation of a tumor for treatment as taught by Carroll when the device taught by Stone et al., Carden, Jr. et al., Shu and Kelderman et al. is used for the treatment of a tumor.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have printed radiopaque ink onto the hose taught by Stone et al., Carden, Jr. et al., Shu and Kelderman et al. via inkjet printing technology since it is well known to print radiopaque ink onto a medical device via inkjet printing technology as taught by Carden, Jr. et al. and to have used an inkjet ink comprising ethanolamine oleate iopamidole as the ink so that the ink may contribute to the preparation of a tumor for treatment as taught by Carroll when the device taught by Stone et al., Carden, Jr. et al., Shu and Kelderman et al. is used for the treatment of a tumor.

10. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. in view of Carden, Jr. et al. and in further view of Shu and in further view of Gundlach et al.

Stone et al., Carden, Jr. et al. and Shu teach the hose as discussed above.

Stone et al., Carden, Jr. et al. and Shu fail to explicitly teach that the ink contains an iodine compound and that the ink contains potassium brodide.

Carden, Jr. et al., however, disclose an implantable biomedical plastic strand (item 900, Fig. 11) that comprises bands of radiopaque ink that are printed onto the plastic strand via inkjet printing technology (col. 20, lines 30-35 and col. 21, lines 14-23). Furthermore, Gundlach et al. disclose an inkjet ink that comprises potassium bromide (col. 38, lines 1-42 and col. 1, lines 5-9) as a salt (col. 17, line 66-col. 18, line 1 and col. 19, lines 17-23) that improves the solubility or stability of the dye in the ink vehicle (col. 20, lines 20-27). Therefore, one of ordinary skill in the art would have recognized to have printed radiopaque ink onto the hose taught by Stone et al., Carden, Jr. et al. and Shu via inkjet printing technology since it is well known to print radiopaque ink onto a medical device via inkjet printing technology as taught by Carden, Jr. et al. and to have used an inkjet ink comprising potassium bromide as the ink since potassium bromide is a well known additive to inkjet ink for improving the solubility or stability of the dye in the ink vehicle as taught by Gundlach et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have printed radiopaque ink onto the hose taught by Stone et al., Carden, Jr. et al. and Shu via inkjet printing technology since it is well known to print radiopaque ink onto a medical device via inkjet printing technology as taught by Carden, Jr. et al. and to have used an inkjet ink comprising potassium bromide as the ink since potassium bromide is a well known additive to inkjet ink for improving the solubility or stability of the dye in the ink vehicle as taught by Gundlach et al.

Response to Arguments

11. Applicant's arguments presented on pages 6-8 of Amdt. B regarding the 35 U.S.C. 103 rejection of claim 14, which now applies to the 35 U.S.C. 103 rejection of claim 1, have been fully considered but are not persuasive.

Applicant argues that Stone et al. "does not suggest that the marker bands each include more than one letter and/or more than one number", but the recitation "each marking section comprising more than one letter and/or more than one number" is a printed matter limitation that has not been given patentable weight based upon the guidelines set forth in MPEP 2112.01 III. The actual form of the markings does not define or contribute to the function of the device. The recitation "each marking section comprising more than one letter and/or more than one number" does not recite a new and unobvious functional relationship between the printed matter and the substrate; therefore, the printed matter recitation "each marking section comprising more than one letter and/or more than one number" bears no patentable weight. *In re Gulack.* Furthermore, the fact that the claims fail to specify which languages, which numbering systems and/or code equivalents (Morse code, Braille, bar, etc...), if any, fall within the scope of the recitation "each marking section comprising more than one letter and/or more than one number" further supports the fact that the content/shape of the markings is not germane to the function of the device and therefore that these shape/content features bear no patentable weight.

Applicant argues that "Stone discloses that the marker bands can be located at the proximal and/or distal regions of the sheath to enable visualization of the axial position of the sheath relative to other structures" in a way that suggests that this is the only possible location of the markers, but the teaching of Stone at col. 5, lines 43-45 is clearly an example ("Preferably",

"such as") of a possible location, not the only possible location. Applicant's description of Stone's teaching of the purpose of the markers bands is also not completely accurate: Stone et al. teach that the marker bands enable visualization of the axial position of the sheath relative to other radiopaque structures (col. 5, lines 47-50), not all "other structures", as Applicant's characterization of the teaching of Stone suggests.

Carden need not disclose that "each marking section comprising more than one letter and/or more than one number" since this recitation is not entitled to patentable weight as discussed above. MPEP 2112.01 III.

Applicant argues that "Stone locates the marker bands at one end, or at both ends, of the sheath to indicate the position of the end(s)", but Stone does not explicitly limit the location of the marker bands to this location since the teaching of Stone at col. 5, lines 43-45 is clearly an example ("Preferably", "such as") of a possible location, not the only possible location. Applicant argues that "Stone does not suggest that it would be desirable to have marker bands arranged longitudinally along the sheath", but the teaching of Stone et al. that the marker bands enable visualization of the axial position of the sheath relative to other radiopaque structures (col. 5, lines 47-50) clearly "suggest[s] that it would be desirable to have marker bands arranged longitudinally along the sheath".

Since Stone et al. teach that the marker bands enable visualization of the axial position of the sheath relative to other radiopaque structures (col. 5, lines 47-50), one of ordinary skill in the art would have recognized to have applied the radiopaque bands of Stone et al. in a longitudinally spaced relationship with one another in a recurring mode of arrangement along the hose of Stone et al. in order to enable a healthcare worker to precisely visualize the location of

the hose within the body and of particular portions of the hose along its length (relative to other radiopaque structures as taught by Stone et al.) since it is well known to provide a medical implant with radiopaque markers in a longitudinally spaced relationship with one another in a recurring mode of arrangement for visualization of the device as taught by Carden, Jr. et al.

12. Applicant's arguments presented on pages 9-11 of Amdt. B regarding the remainder of the 35 U.S.C. 103 rejections depend upon Applicant's arguments presented on pages 6-8 of Amdt. B regarding the 35 U.S.C. 103 rejection of claim 14, which have been addressed above in this Office Action.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is (571) 272-1488. While the examiner sets his work schedule under the Increased Flexitime Policy, he can normally be reached on Monday-Friday from 8:45am to 5:15pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on (571) 272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Walter B. Aughenbaugh
04/30/07

Walter B Aughenbaugh
4/30/07